Commonwealth of Massachusetts
Division of Registration
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COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY
NOTICE OF RESOLUTION OF COMPLAINT COMMITTEE

To: Barry J. Cadden, R.Ph.
32 Rhodes Street
Cumberland, RI 02864

In the Matter of: Barry J. Cadden, R.Ph., Pharmacist Registration No. 21239 ("Registrant") and New England Compounding Center of Waverly Street, Framingham, Massachusetts, Permit No 2848.

The Board of Registration in Pharmacy received a complaint from a Board Agent alleging that a pharmacist, Barry J. Cadden, R.Ph., License No. 21239 (" Registrant") and New England Compounding Center provided a practitioner with prescription blanks which referred to the New England Compounding Center, in violation of Board Regulations at 247 CMR § 9.01 (13) and 9.01 (1).

The Board Complaint Committee reviewed the complaint on Tuesday, October 19, 1999 including investigative material submitted by the Agent of the Board . The Board voted to issue an Informal Reprimand to Registrant and New England Compounding Center.

This decision is not considered formal action. The complaint and any materials generated as a result of the investigation of the complaint will remain on file with the Board as it is a matter of public record.

PER ORDER OF THE BOARD
Harold B. Sparr

Harold Sparr, R.Ph., President
Board of Registration in Pharmacy

c: Complainant
Certified Mail Number: z 049 085 540
Dated: October 27, 1999

EXHIBIT NO. 718

New England Compounding Center, Framingham
Complaints and Inspections

- Complaint 19990330PH066: October 27, 1999, the Board of Pharmacy issued an Informal Reprimand (non-disciplinary) letter to NECC in resolution of a complaint that found that NECC had provided a practitioner with prescription blanks that included a reference to NECC.

- Complaints regarding Inspection findings DS-03-055: October 24, 2002, the Board of Pharmacy and FDA conducted a **joint investigation at NECC related to three FDA MedWatch reports that FDA had received detailing adverse events that occurred in two patients in July 2002 at the Park Ridge Hospital (PRH) in Rochester, NY associated with the use of methylprednisolone acetate preservative free 80 mg/ml that was compounded by NECC in May 2002.** Two of the three MedWatch complaints were reported by a physician and Chief Pharmacist at PRH. The Board does not have copies of the MedWatch reports, but the FDA's 2/10/03 report, which was provided to the Board, provides a description of the adverse events as described by a Quality Supervisor of PRH. The FDA report states that both PRH patients were given injections of methylprednisolone acetate on 7/17/02 from the same lot and both experienced pain and headache and were hospitalized with meningitis-like symptoms. Both patients received antibiotic therapy and cultures of both patients' cerebrospinal fluid (CSF) were negative. Both patients fully recovered. NECC conducted a recall following the 7/17/2002 events in August 2002, but had not notified the FDA of the recall. FDA report also states, "…8/22/02 hard copy [reports of NECC] showed negative for "endotoxin content and microbial contamination". The FDA closed its investigation on February 10, 2003 and submitted a copy of its report to the Board of Pharmacy on March 13, 2003. This FDA investigation report also references concerns and test results indicating sub-potency issues with betamethasone repository (betamethasone sodium phosphate and betamethasone acetate).

  As a result of the joint inspection, the Board opened a complaint against NECC and required NECC to correct all deficiencies. The Board conducted a follow-up inspection and verified correction of all deficiencies on February 20, 2004. Even though, NECC had corrected the deficiencies, the Board moved forward on the fact that the deficiencies existed in 2002/2003. In settlement of the Board complaint, NECC entered into a 1/6/2006 *Consent Agreement* with the Board that required NECC to hire a Board-approved independent evaluator PSI (Pharmaceutical Systems, Inc./Pharmacy Support Systems, Inc.) to conduct an inspection of NECC's compounding practices and compliance with USP Standard 795 for Non-Sterile Compounding Procedures and USP Standard 797 for Sterile Compounding Procedures and required NECC to comply with all recommendations of the evaluator. Areas to be reviewed by the evaluator, included, but were not limited to: Sterile Environmental Design, Quality Assurance Program, Media Fills (operator qualifications/process validation), Environmental Monitoring, Cleaning and Sanitizing Program, Training Records, Process Controls, and Equipment. The evaluator conducted on-site inspections in the course of the evaluation and did follow-up visits on March 8th, 9th and 10th, 2006. On 6/2/2006, the Board advised

NECC that it had satisfactorily completed the terms and conditions of the Consent Agreement.

- Complaint DS-03-060: In 2003, the Board received a complaint that NECC had sent unapproved solicitations regarding intravitreal triamcinolone acetonide that included promotional material and terminology in the advertisement. On 9/30/2004, the Board issued an advisory letter resolving this complaint.

- Complaint DS-03-036: In 2003, the Board investigated a complaint concerning NECC solicitation forms provided to prescribers for office use that included a prescription form that was unapproved by the DPH and Board. On 9/30/2004, the Board issued and advisory letter resolving this complaint.

- Complaint DS-04-062: In 2004, the Board received a complaint that NECC was providing out-of-state prescriptions for office use and using a form unapproved by DPH and the Board. On 9/30/2004, the Board issued an advisory letter resolving this complaint.

- Complaint DS-05-040: In 2004, the Board received a complaint that NECC was dispensing a product without a valid (patient specific) prescription. This complaint was included in the 1/06/2006 *Consent Agreement* (with Complaint DS-03-055).

- Inspection on May 24, 2011; the Board inspected the pharmacy following renovation and expansion at the existing location. No deficiencies were cited.